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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,936	01/03/2000	THOMAS G. WILSON	082584/0107	6645
29052	7590	05/04/2004	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP			GUZO, DAVID	
999 PEACHTREE STREET, N.E.			ART UNIT	
ATLANTA, GA 30309			PAPER NUMBER	
			1636	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,936

Applicant(s)

WILSON ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-28,30-41,44-47 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 30-41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,20-22 and 27 is/are allowed.
- 6) ☒ Claim(s) 9-14,19,23-26,44-47 and 51 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Drawings

The drawings filed 2/20/04 are objected to. Specifically, Figs. 2-5 contain letters and reference characters which are not at least .32 cm or 1/8th inch in height (37 CFR 1.84(p)(3)). Applicant is required to submit the drawing corrections within the time period set in this Office Action (See 37 CFR 1.85(a)). Corrections to the drawings will no longer be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-14, 44-47, 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,326,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

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Applicants do not traverse this rejection but instead indicate that if it is maintained after consideration of the instant amendments, they will file a Terminal Disclaimer. The instant amendments do not change the issues with regard to double patenting over claims 1-23 of the '165 patent. The patented claims still anticipate the instant claims because the instant claims are generic to the patented claims and encompass all that is claimed in the '165 patent. The rejection is therefore maintained.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants, in Claim 51, recite an isolated insect polynucleotide that encodes a bHLH-PAS polypeptide involved in binding JH III wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO:7. SEQ ID NO:7 is a 232 nucleotide portion of a putative *Drosophila erecta* bHLH-PAS gene which shows a high degree of homology to a portion of a bHLH-PAS gene from *D. melanogaster* and which encodes an N-terminal portion of a putative bHLH-PAS polypeptide. The claim reads on a genus of

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polynucleotide sequences which encode bHLH-PAS polypeptides which are involved in binding JH III wherein said polypeptide hybridizes under stringent conditions to SEQ ID NO:7.

Applicants, in Claim 19, recite a method for screening compounds that specifically bind with a complex comprising a bHLH-PAS polypeptide that is involved in binding JH III and a heteromultimeric partner of said polypeptide wherein said method requires an isolated heteromultimeric partner of the bHLH-PAS polypeptide. The claims read on a genus of heteromultimeric partners of bHLH-PAS polypeptides wherein said bHLH-PAS polypeptides are encoded by polynucleotides which hybridize under stringent conditions to SEQ ID NO: 1, 2, 3 or 6.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the case of Claim 51, applicants disclose a portion of the sequence encoding a N-terminal region of a putative *D. erecta* bHLH-PAS polypeptide. Applicants present no information as to whether **said portion** encodes a polypeptide which is involved in binding JH III. Essentially, applicants are claiming sequences which encode a bHLH-PAS polypeptide that binds JH III wherein said sequence hybridizes to SEQ ID NO:7

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under stringent conditions, wherein it is unknown if SEQ ID NO:7 actually encodes a polypeptide which is involved in binding JH III. Given the absence of a disclosure on whether SEQ ID NO:7 actually encodes a polypeptide capable of binding JH III, it must be considered that applicants have not disclosed a genus of molecules capable of hybridizing to SEQ ID NO:7 and binding JH III. The structures of nucleotide sequences having SEQ ID NO:7 or sequences which hybridize to SEQ ID NO:7 under stringent conditions and which encode polypeptides which bind JH III are unknown and are not taught or suggested by the structure of SEQ ID NO:7. The specification discloses a single common structural feature shared by members of the genus, i.e. SEQ ID NO:7. Since the claimed genus encompasses bHLH-PAS genes capable of hybridizing to the portion of the *D. erecta* putative bHLH-PAS encoding sequence, genes yet to be discovered, DNA constructs that encode fusion proteins, etc. the disclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore the disclosure of SEQ ID NO:7 does constitute a representative number of species sufficient to describe the claimed genus.

In the case of Claim 19, applicants provide no disclosure of any heteromultimeric partners of any bHLH-PAS polypeptides encoded by the recited nucleotide sequences. Applicants claim these molecules by function only with no correlation between the function of these molecules and their structure. The function of these molecules to bind the recited bHLH-PAS polypeptides provides no disclosure of the structure of these molecules. Given the absence of any disclosure on the structure of the molecules

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which make up the recited genus, the skilled artisan would not have concluded that applicants were in possession of the claimed genus.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is vague in that there is no antecedent basis for the term "said receptor" in claim 18.

Claim 24 (and dependent claims) are vague in that there is no antecedent basis for the term "said detectably labeled ligand" in claim 18.

Claim Objections

Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 28 recites that the polypeptide used in the method of claim 18 is "a polypeptide having **an** (emphasis added) amino acid sequence of SEQ ID NO:4"; however, claim 18 recites that the polypeptide used is encoded by a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:3 (which encodes

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SEQ ID NO:4). The phrase "an amino acid sequence of SEQ ID NO:4" reads on a polypeptide which comprises any amino acid sequence of any size (i.e. peptides of 2 or 3 or 5 amino acid residues) from SEQ ID NO:4. Therefore, this limitation is broader than the scope of the claim from which it depends.

Miscellaneous

A nucleotide sequence on p. 66 of the specification has not been identified by SEQ ID NO identifier. Any response that does not include complete compliance with the Sequence Rules will be considered nonresponsive.


Claims 18, 20-22 and 27 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
April 26, 2004


DAVID GUZO
PRIMARY EXAMINER